

15 May 1999

5468 '99 MAY 21 P2:21

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

RE: Docket No. 98N-1265

To the FDA:

I am writing this letter as a consumer of healthcare services to register my concern and total disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of patients and physicians to obtain healthcare products from the provider of their choice. It also infringes upon the rights of compounding pharmacists to serve the public's medical needs. I cannot tolerate the current pharmaceuticals for HRT because of their side effects, so am most grateful for the natural plant hormones as compounded by pharmacists who provide these services. As a healthcare consumer, I strongly believe there should be no restrictions to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel. The MOU must be amended!

The FDA is an agency of the US Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!!! As a governmental agency, the FDA also has a responsibility to be accountable to us, the people.

Once again, the MOU must be amended.

Sincerely,



Marilyn O'Callaghan
P.O. Box 129
Winthrop, WA 98862
cc: Senator Gorton, Senator Murray & Representative Hastings

98N-1265

C 2472